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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,241

09/16/2003

Pal Maliga

RUT.97-0097US1-DIV

5658

110 7590 03/21/2007  
DANN, DORFMAN, HERRELL & SKILLMAN  
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PHILADELPHIA, PA 19103-2307

EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/663,241

Applicant(s)

MALIGA ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 January 2007 has been entered.
2. Claims 1-11 are pending. Claims 1-4 are withdrawn from consideration as being drawn to non-elected inventions.
3. This application contains claims 1-4 drawn to an invention nonelected with traverse in the response filed 18 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

5. Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is only support in Example 1 and Fig 5 for clpP, rpoB and atpP NEP promoters from a small number of plant species, not from any plant species as encompassed by the claims. Example IV only provides support for the rbcL, atpB, clpP and 16SrDNA PEP promoters from

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rice, not from any plant species as encompassed by the claims.

Thus, the recitation of these promoters constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the recitation or to cancel the new matter.

6. Claims 5 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 4 May 2006, as applied to claim 5, due to Applicant's amendment of the claims. Applicant's arguments filed 7 August 2006 have been fully considered but they are not persuasive.

A full review of the specification indicates that nucleic acids comprising NEP and PEP promoters are essential to the operation of the claimed invention. Further, claims 10-11 indicate that the constructs comprise *clpP*, *rpoB* or *atpB* NEP promoters from any source and/or *rbcL*, *atpB*, *clpP* and 16SrDNA PEP promoters from any source.

The level of skill and knowledge in the art at the time of filing was such that only a few of such promoters were identified; thus, there is no well-developed field of prior art.

The specification describes a NEP promoter consensus that is present in some, but not all NEP promoters (pg 21-22). No PEP consensus is described. Thus, the necessary and sufficient structural elements of the claimed promoters are not described within the full scope of the claims.

Hence, Applicant has not, in fact, described nucleic acids that comprise NEP and PEP promoters within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the

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structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges they disagree with examiner's positions for the reasons previously presented (response pg 5).

This is not found persuasive for the reasons previously presented.

Applicant urges that the recited function is that an NEP promoter is transcribed by a nuclear-encoded plastid polymerase and a PEP promoter is transcribed by a plastid encoded polymerase, thus the function of NEP and PEP promoters are provided (response pg 5-6).

This is not found persuasive because structural and functional elements of the claimed promoters must be described. The structural elements are not described within the full scope of the claims. The specification describes an NEP promoter consensus that is present in some, but not all NEP promoters (pg 21-22). No PEP consensus is described.

Applicant urges that a single species can describe a genus, citing Example 9 of the written description guidelines (response pg 6).

This is not found persuasive because in example 9, more than one DNA was isolated and shown to encode proteins with the specified activity. The claims were not drawn to any DNA that encode proteins with the specified activity, but to a subset of them. The instant case does not follow the fact pattern of Example 9. In the instant case, the instant claims are drawn to any promoter with the claimed functions. Such promoters are not described within the full scope of the claims.

Applicant urges that they describe multiple species of NEP and PEP promoters (response pg 6).

This is not found persuasive because NEP and PEP promoters were only described from a

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few genes and from a few plant species. Further, the specification could not describe the structural features in common with NEP promoters and in common with PEP promoters.

7. Claims 5 and 9-10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain constructs comprising both NEP and PEP promoters, does not reasonably provide enablement for all constructs comprising both NEP and PEP promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 4 May 2006, as applied to claim 5, due to Applicant's amendment of the claims. Applicant's arguments filed 7 August 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to any construct comprising both NEP and PEP promoters, including constructs comprising *clpP*, *rpoB* or *atpB* NEP promoters from any source and/or *rbcl*, *atpB*, *clpP* and 16SrDNA PEP promoters from any source.

The instant specification, however, only provides guidance for analysis of plastid transcription in wildtype and *rpo*<sup>-</sup> mutants, and the identification of NEP promoters from *clpP*, *rpoB*, *atpB* (example 1), and the PEP promoters from *clpP* (example 2-3); and promoter mapping in rice plastids (example 4).

The instant specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB* and *atpB* from a small number of species, and for PEP promoters from genes other than rice *clpP*.

As the specification does not describe NEP and PEP promoters within the full scope of the claims, undue trial and error experimentation would be required to screen through the myriad

of nucleic acids encompassed by the claims, to identify those that are NEP and PEP promoters, if such plants are even obtainable.

Applicant urges that examples I-IV provide methods for identification of NEP and PEP promoters; thus, no undue experimentation is required (response pg 6-7).

This is not found persuasive because the examples do not teach how to make the claimed promoters, only how to assay them. Since the specification fails to teach how to make the promoters, undue trial and error experimentation would be required to make and test potential nucleic acids.

#### ***Claim Rejections - 35 USC § 102***

8. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Maliga et al (US Patent 5,877,402, filed January 1994), taken with the evidence of Legen et al (2002, Plant J. 31:171-188). The rejection is repeated for the reasons of record as set forth in the Office action mailed 4 May 2006. Applicant's arguments filed 7 August 2006 have been fully considered but they are not persuasive.

Maliga et al teach constructs comprising the *rps16* promoter operably linked to the *uidA* coding region (Fig 22A and C). Legen et al teach that this promoter comprises NEP and PEP promoters (paragraph spanning the columns on pg 179).

Applicant urges that Legen et al is wholly silent as to the presence of an NEP promoter in the *rps16* promoter, and that the higher transcription rates seen in wild-type leaf tissue can be accounted for by a promoter containing only a PEP promoter, because such a promoter would exhibit higher relative transcription rates in wild-type than mutant leaf tissue (response pg 7-8).

This is not found persuasive because Legen states that all plastid genes are transcribed in

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e PEP-deficient background (paragraph spanning the columns on pg 176). Thus, the rps16 promoter is both a PEP and an NEP promoter.

9. Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.


The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D.  
March 6, 2007



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER